



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

APR 25 2000

Laurie J. Smidt, Ph.D., R.D.  
Owner  
TheraNutria  
636 S. 1450 East  
Springville, Utah 84663

Dear Dr. Smidt:

This is in response to your letter to the Food and Drug Administration (FDA), dated April 11, 2000. Your letter responded to our letter of March 14, 2000 that discussed your previous submission for claims being made for the product Glucovite that was submitted pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your current letter contained the following claims:

“Glucovite comprehensively addresses the vitamin and mineral requirements of individuals who are concerned with normal blood sugar levels and glucose tolerance.”  
“Glucovite helps promote healthy blood sugar levels when used as part of your diet.”  
“Glucovite helps promote normal glucose tolerance when used as part of your diet.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely disorders of glucose tolerance and blood glucose levels<sup>1</sup>. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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<sup>1</sup>You may wish to consult the preamble discussion for the final rule published in the January 6, 2000 Federal Register (65 FR 1000 at 1015) that addresses claims about the signs or symptoms of disease.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Denver District Office, Compliance Branch, HFR-SW240

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (file, r/f)  
HFS-811 (r/f, file)  
HFD-40 (Behrman)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Betz)  
GCF-1 (Barnett, Nickerson, Dorsey)  
f/t:rjm:HFS-811:4/24/00:70316.adv:disc46

# TheraNutria

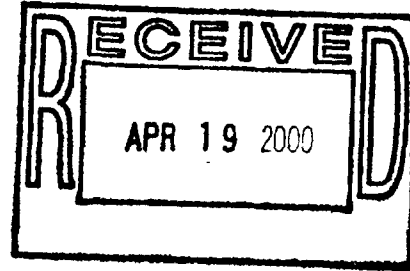
636 S. 1450 East  
Springville, UT 84663

Tel.: 801-491-0565  
Fax: 801-491-0566

**Glucovite<sup>®</sup>**

April 11, 2000

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
200 C St. SW  
Washington, DC 20204



RE: Your Letter of March 14, 2000

Dear Mr. Foret:

I received your letter of March 14, 2000, which explained that our first submission of February 19, 2000, of claims for our product "Glucovite" contained several claims that suggested that Glucovite may be intended to treat, prevent, or mitigate disease, namely diabetes and disorders of glucose tolerance, and that such claims do not meet the requirements of 21 U.S.C. 343(r)(6).

Since we do intend to market Glucovite as a dietary supplement product and not as a drug, we will revise the original claims in response to your letter as described below with our next production run of new product.

Revised Claims: Product identified as "Glucovite" with the following label statements:

- Glucovite comprehensively addresses the vitamin and mineral requirements of individuals who are concerned with normal blood sugar levels and glucose tolerance.
- Glucovite provides optimum antioxidant protection to promote healthy eye, nerve and circulatory functions.
- Glucovite helps promote healthy blood sugar levels when used as part of your diet.
- Glucovite helps promote normal glucose tolerance when used as part of your diet.

I certify that the information contained in this notice is complete and accurate and that TheraNutria has substantiation that these statements are truthful and not misleading.

Sincerely,

Laurie J. Smidt, Ph.D., R.D.  
Owner, TheraNutria